REMARKS

Claims 1-9 are pending in the instant application. Claims 1-9 have been rejected. Claims 2 and 4 through 9 have been canceled. Claims 1 and 3 have been amended. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims Under 35 U.S.C. 112, Second Paragraph

Claims 2, 6, and 8 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2, 6 and 8 have been canceled making the rejection as it pertains to these claims moot. With respect to the term "testosterone derivative", at page 16, lines 33-34, the term "testosterone derivative" is defined, reciting several specific compounds. As a result, the specification as filed provides one of skill in the art with an understanding of what is considered a "testosterone derivative". However, in an earnest effort to advance the prosecution of this case, Applicant has amended the pending claims to refer to the specific derivatives listed on page 16 of the specification as filed. Therefore, the claims as amended meet the requirements of 35 U.S.C. 112, second

paragraph. Withdrawal of this rejection is, therefore, respectfully requested.

II. Double Patenting

Claims 1-9 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-8, 10 and 13 of copending U.S. Application No. 10/464,310. Since the scope of the claims may change during prosecution, Applicants request that this rejection be held in abeyance until one of the claim sets has been allowed.

III. Rejection of Claims Under 35 U.S.C. 102(b)

The rejection of claims 1, 2 and 4 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,935,949 has been maintained. The Examiner suggests that this patent discloses a method of treating fibromyalgia by employing an androgen and DHEA, a testosterone derivative, and that one of the symptoms of fibromyalgia is muscle pain. Applicants respectfully traverse this rejection.

At the outset, claims 2 and 4 have been canceled making this rejection as it pertains to those claims moot. Further, in

an earnest effort to advance the prosecution of this case, Applicant has amended claim 1 to recite that the method of the instant invention employs a unit dose of testosterone or a testosterone derivative which is administered to a woman. Support for these amendments can be found at page 9, lines 14-23. These amendments distinguish the instant invention as a unit dose shown to be effective in relieving symptoms of muscle pain in women.

Also with respect to claim 1, and as discussed in the previous reply dated February 27, 2006, U.S. Patent No. 5,935,949 is also an invention by Dr. Hillary White. This patent discloses the specific use of an androgen, either alone or as a combination of androgens or androgen derivatives, to treat one of two specific diseases or syndromes, fibromyalgia and chronic fatigue syndrome. Chronic muscle pain, however, is not the same condition as fibromyalgia or chronic fatigue syndrome, which are more specific and defined conditions that involve more than just muscle pain. Nowhere does this patent teach or suggest that an androgen of any type is useful solely for treatment of muscle pain or muscle wasting.

Muscle pain and muscle wasting, as now claimed, are found in the specification as filed under a discussion of the issue of general muscle pain and wasting at page 16, lines 14-29. There

it is clearly pointed out that apart from fibromyalgia, the instant invention has application to treatment of muscle pain. Further, the specification as filed provides data specific to the issue of muscle pain, the tender point analysis (see pages 13-15), data that was not taught in the prior art patent (5,935,949). Therefore, the present invention is a specific assessment of the effect of androgen treatment on a specific endpoint, muscle pain. One of skill in the art would appreciate that fibromyalgia and muscle pain, more generally, are not the same condition.

MPEP 2131 states that in order to anticipate an invention the cited reference must teach each and every limitation of the claims. Clearly, the reference cited fails to teach the limitations of the claims as amended which recite muscle pain by itself, not a more complicated disease, fibromyalgia, and alleviation of those symptoms with a unit dose of testosterone or a testosterone derivative. Accordingly, withdrawal of this rejection is respectfully requested.

IV. Rejection of Claims Under 35 U.S.C. 103(a)

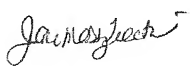
Rejection of claims 3 and 5-9 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,935,949, in view of U.S. Patent No. 5,656,606 has been maintained. Applicant has

canceled claims 5-9 and removed the language from claim 3 that refers to hexarelin or IGF-1. Accordingly, this rejection of the claims is moot. Withdrawal of this rejection is therefore respectfully requested.

V. Conclusion

Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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